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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Yolanda Munoz, an individual, Plaintiff, vs. Cook Incorporated; Cook Medical Incorporated; Cook Group Incorporated; Cook Medical, LLC, Defendants.	CASE NO. _____ **COMPLAINT** JURY TRIAL DEMANDED

Plaintiff Yolanda Munoz, by and through undersigned attorneys, hereby sues Defendants Cook Incorporated, Cook Medical Incorporated, Cook Group Incorporated, and Cook Medical, LLC, and alleges as follows:

PARTIES

1. Plaintiff Yolanda Munoz (hereinafter "Plaintiff") at all times relevant to this action resided in, continues to reside in, and is a citizen of Maricopa County, Arizona.

2. Defendant Cook Incorporated was and is an Indiana corporation with its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402. At

all times relevant to this action, Cook Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold the inferior vena cava filter ("IVC Filter") known as the Gunther Tulip™ Vena Cava Set (hereinafter "Cook filter") to be implanted in patients throughout the United States, including Arizona. At all times relevant hereto, Defendant Cook Incorporated was engaged in business in Arizona, has conducted substantial business activities, and derived substantial revenue from within the State of Arizona. This Defendant has also carried on solicitations or service activities in Arizona.

3. Defendant Cook Medical Incorporated is a wholly owned subsidiary of Defendant Cook Incorporated with its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402. Defendant Cook Medical Incorporated was and is an Indiana corporation authorized and/or doing business in the state of Arizona. At all times relevant to this action, Cook Medical Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold the IVC Filter known as the Gunther Tulip™ Vena Cava Set to be implanted in patients throughout the United States, including Arizona. At all times relevant hereto, Defendant Cook Medical Incorporated was engaged in business in Arizona, has conducted substantial business activities, and derived substantial revenue from within the State of Arizona. This Defendant has also carried on solicitations or service activities in Arizona.

4. Defendant Cook Group Incorporated was and is an Indiana corporation having its principal place of business located at 750 Daniels Way, Bloomington, Indiana

47402. At all times relevant to this action, Cook Group Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and sold the IVC Filter known as the Gunther Tulip™ Vena Cava Set to be implanted in patients throughout the United States, including Arizona. At all times relevant hereto, Defendant Cook Group Incorporated was engaged in business in Arizona, has conducted substantial business activities, and derived substantial revenue from within the state of Arizona. This Defendant has also carried on solicitations or service activities in Arizona.

5. Defendant Cook Medical, LLC was and is an Indiana limited liability corporation with its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402 with its sole member being Cook Incorporated and maintains its principal place of business located at 750 Daniels Way, Bloomington, Indiana 47402. At all times relevant to this action, Cook Medical, LLC designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold the IVC Filter known as the Gunther Tulip™ Vena Cava Set to be implanted in patients throughout the United States, including Arizona. At all times relevant hereto, Cook Medical, LLC was registered to do business with the state of Arizona. At all times relevant hereto, Defendant Cook Medical LLC was engaged in business in Arizona, has conducted substantial business activities, and derived substantial revenue from within the state of Arizona. This Defendant has also carried on solicitations or service activities in Arizona.

6. Defendants Cook Incorporated, Cook Medical Incorporated, Cook Group Incorporated, and Cook Medical, LLC, shall be referred to herein individually by name or collectively as the "Cook Defendants."

7. At all times alleged herein, Cook Defendants include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

8. At all times herein mentioned, each of the Cook Defendants were the agents, servants, partners, predecessors in interest, and joint venturers of each other, and were at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, joint enterprise, and/or joint venture.

JURISDICTION AND VENUE

9. Jurisdiction is proper in this court under 28 U.S.C.§ 1332(a)(1) because the Plaintiff and the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00), exclusive of interest and costs.

10. Venue is proper in this court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred within this judicial district and the Defendants regularly conduct business in this district.

GENERAL FACTUAL ALLEGATIONS

11. Plaintiff brings this case against the Cook Defendants because of the serious, life-threatening injury she has suffered as a result of the Cook Defendants' surgically

implanted medical device, the Cook Gunther Tulip™ filter, that was implanted by Brian W. Zernich, D.O., at Banner Casa Grande Medical Center in Casa Grande, Arizona on or about October 21, 2009.

12. Cook Defendants design, research, develop, manufacture, test, market, advertise, promote, distribute, and sell IVC filters, which are marketed and sold as both permanent and retrievable devices, purportedly to prevent recurrent pulmonary embolism. One such product is the Cook Gunther Tulip™ IVC filter at issue in this case.

13. To date, there is no evidence to support the notion that IVC filters offer any clinical benefit to patients.

14. Cook Defendants sought Food and Drug Administration ("FDA") clearance to market the Cook Gunther Tulip™ filter device and/or its components under Section 510(k) of the Medical Device Amendment.

15. On or about October of 2000, the Cook Defendants obtained FDA clearance to market the Cook Gunther Tulip™ filter under Section 510(k) of the Medical Device Amendment as a permanent IVC filter.

16. On or about October 31, 2003, the Cook Defendants obtained FDA clearance to market the Cook Gunther Tulip™ under Section 510(k) of the Medical Device Amendment as a retrievable IVC filter.

17. Section 510(k) allows marketing of medical devices if the manufacturer claims the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of said device. The device is then cleared

by the FDA under Section 510(k). The Cook Defendants claimed that the Gunther Tulip™ filter was substantially equivalent to the Greenfield and LGM Vena Tech IVC filters.

18. An IVC filter, like the Cook Gunther Tulip™ filter, is a device ostensibly designed and intended to filter blood clots (called "thrombi") that would otherwise travel from the lower portions of the body to the heart and lungs, resulting in a pulmonary embolism (PE). IVC filters are marketed as being safe to implant, either temporarily or permanently, within the vena cava.

19. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava and into the heart and lungs. These thrombi can develop in the deep leg veins. This condition is called "deep vein thrombosis" or DVT. If the thrombi reach the lungs they are considered "pulmonary emboli" or PE.

20. The Gunther Tulip™ filter is a retrievable filter and is alleged by Cook as being substantially similar to the Cook Defendants' Gunther Tulip™ filter, its predicate device.

21. The Gunther Tulip™ filter has four (4) anchoring struts for fixation with webbed wires (like Tulip™ petals) between each of the anchoring structs

22. On or about October 21, 2009, Plaintiff was implanted with a Cook Gunther Tulip™ IVC filter at Banner Casa Grande Medical Center in Casa Grande, Arizona, by Brian W. Zernich, D.O. The Cook Gunther Tulip™ filter placed in Plaintiff was marked and sold as appropriate for use as either a retrievable or a permanent filter.

23. Plaintiff has suffered serious injury as a result of the implantation of the Cook Gunther Tulip™ filter. Specifically, several prongs of the Cook Gunther Tulip™ filter have perforated Plaintiff's IVC. Struts further perforate and abut other structures in Plaintiff's body. The filter has also tilted substantially. Plaintiff is at risk for future progressive perforations by the Cook Gunther Tulip™ filter which could further injure adjacent organs, blood vessels, and structures, as well as fracturing of the IVC filter and migration of the Cook Gunther Tulip™ filter or pieces thereof. Plaintiff faces numerous health risks, including the risk of death. Plaintiff will require ongoing medical care and monitoring for the rest of her life. It is unknown if the filter can be retrieved by any means other than an open surgical procedure.

24. At all times relevant hereto, the Cook Gunther Tulip™ filter was widely advertised and promoted by the Cook Defendants as safe and effective for prevention of recurrent pulmonary embolism.

25. At all times relevant to this complaint, the Cook Defendants knew or should have known that the Cook Gunther Tulip™ IVC filter was defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

26. The Cook Defendants failed to disclose to physicians, patients, or Plaintiff that its retrievable IVC filters, including the Cook Gunther Tulip™ filter, were subject to perforation through the IVC wall, fracture, and migration or the appropriate degree of risk of perforation and damage to the vena cava wall and surrounding organs, blood vessels, and structures.

27. At all times relevant hereto, the Cook Defendants continued to promote Cook's retrievable IVC filters, including the Cook Gunther Tulip™ filter, as safe and effective even though the clinical trials that had been performed were not adequate to support long- or short-term safety or efficacy.

28. Cook Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook retrievable IVC filters, including the Cook Gunther Tulip™ filter, as aforesaid.

29. The failure of the Cook filter is attributable in part to the fact that the Cook retrievable IVC filters, including the Cook Gunther Tulip™ filter, suffer from a design defect causing the filters to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.

30. At all times relevant hereto, the Cook Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Gunther Tulip™ filter, including, but not limited to, the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

31. The Cook Gunther Tulip™ filter was designed, manufactured, distributed, marketed, promoted, sold, and/or supplied by Cook Defendants and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Cook Defendants' knowledge of the product's failure and serious adverse events.

32. At all times relevant hereto, the officers and/or directors of the Cook Defendants named herein participated in, authorized, and/or directed the production and

promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

FRAUDULENT CONCEALMENT

33. The Cook Defendants were under a continuing duty to disclose the true character, quality, and nature of the device that was implanted in Plaintiff, but instead they concealed them. The Cook Defendants remain under a continuing duty to disclose the true character, quality, and nature of the device that was implanted in Plaintiff, but instead they continue to conceal them. The Cook Defendants' conduct, as described in this complaint, amounts to conduct purposely committed, which they must have realized was dangerous, heedless, and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

34. At all times herein mentioned, the Cook Defendants were agents, servants, partners, aiders and abettors, co-conspirators, and/or joint venturers, and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and/or joint venture and rendered substantial assistance and encouragement to each other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

35. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the Cook Defendants such that any individuality and separateness between them have ceased and these Defendants are alter egos. Adherence

to the fiction of the separate existence of these Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would not promote injustice.

36. At all times herein mentioned, the Cook Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

37. At all times herein mentioned, the officers and/or directors of the Cook Defendants named herein participated in, authorized and/or directed the production, marketing, promotion, and sale of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

COUNT I
NEGLIGENCE

38. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

39. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing,

promoting, selling, and distributing Cook IVC filters including the Cook Gunther Tulip™ IVC filter.

40. The Cook Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed, and sold the Cook Gunther Tulip™ filter that was implanted in Plaintiff.

41. The Cook Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of Cook IVC filters, including the Gunther Tulip™ filter, so as to avoid exposing others to foreseeable and unreasonable risks of harm.

42. The Cook Defendants knew or reasonably should have known that the Cook Gunther Tulip™ filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

43. At the time of manufacture and sale of the Cook Gunther Tulip™ filter (2000 until Present), the Cook Defendants knew or should have known that the Cook Gunther Tulip™ filter was designed and manufactured so as to present an unreasonable risk of the device tilting and/or perforating the vena cava wall.

44. At the time of manufacture and sale of the Cook Gunther Tulip™ filter (2000 until Present), the Cook Defendants knew or should have known that using the Cook Gunther Tulip™ filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; pericardial effusion; cardiac tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels, and organs; and

other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

45. The Cook Defendants knew or reasonably should have known that consumers of the Cook Gunther Tulip™ filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

46. The Cook Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the Cook Gunther Tulip™ filter in, among others, the following ways:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiff, Plaintiff's physicians, Plaintiff's agents, or the general health care community about the Cook Gunther Tulip™ filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre and post-market testing of the Cook Gunther Tulip™ filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Cook Gunther Tulip™ filter;

g. Advertising, marketing, and recommending the use of the Cook Gunther Tulip™ filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the Cook Gunther Tulip™ filter;

h. Representing that the Cook filter was safe for its intended use when in fact, the Cook Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Cook Gunther Tulip™ filter with the knowledge that said product was dangerous and not reasonably safe;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Cook Gunther Tulip™ filter so as to avoid the risk of serious harm associated with the use of the Cook Gunther Tulip™ filter;

k. Advertising, marketing, promoting, and selling Cook Gunther Tulip™ filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Cook Gunther Tulip™ filter; and,

m. Failing to establish and maintain an adequate post-market surveillance program.

n. Failing to conduct patient studies to determine whether the Cook Gunther Tulip™ filter offers a clinical benefit to patients.

o. Upon learning that IVC filters do not provide any clinical benefit to patients, defendants continued to sell its IVC filters, failed to pull them off the market, failed to notify the medical community to stop implanting its filters and failed to notify patients implanted with filters to have them removed.

47. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

48. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss is yet to be determined.

COUNT II
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

49. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

50. The Cook Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Cook filters, including the Cook Gunther Tulip™ filter implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

51. At the time the Cook Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Gunther Tulip™ filter into the stream of commerce, the Cook Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, the Cook Defendants knew or should have known at the time they manufactured, labeled, distributed, and sold the Cook Gunther Tulip™ filter that was implanted in Plaintiff, that the Cook Gunther Tulip™ filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries.

52. Consequently, the Cook Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

53. The Cook Defendants further had a duty to warn of dangers and proper safety instructions that they became aware of even after the device was distributed and implanted in Plaintiff.

54. Despite their duties, the Cook Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Cook IVC filters, including the Cook Gunther Tulip™ filter, and further failed to adequately provide instructions on the safe and proper use of the device.

55. No health care provider, including Plaintiff's, patient or patient's agent would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

56. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

57. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

58. Therefore, the Cook Gunther Tulip™ filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

59. The Cook Gunther Tulip™ filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed, and sold by the Cook Defendants.

60. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss is yet to be determined.

COUNT III
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

61. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

62. At all times relevant to this action, the Cook Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed, and sold into the stream of commerce the Cook IVC filters, including the Cook Gunther Tulip™ filter implanted in Plaintiff.

63. The Cook Gunther Tulip™ filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left the Cook Defendants' possession. In the alternative, any changes that were made to Cook filter implanted in Plaintiff were reasonably foreseeable to the Cook Defendants.

64. The Cook Gunther Tulip™ filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

65. The Cook Gunther Tulip™ filter could have been designed and manufactured with a stop limiter avoiding unsafe perforation, tilt, and fracture.

66. The Cook Gunther Tulip™ filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

67. Plaintiff and Plaintiff's health care providers used the Cook Gunther Tulip™ filter in a manner that was reasonably foreseeable to the Cook Defendants.

68. Neither Plaintiff, nor Plaintiff's health care providers could have, by the exercise of reasonable care, discovered the device's defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

69. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss is yet to be determined.

COUNT IV
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

70. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

71. The Cook Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Cook IVC filter that was implanted into Plaintiff.

72. The Cook Gunther Tulip™ filter implanted in Plaintiff contained a condition or conditions, which Defendants did not intend, at the time it left the Cook Defendants' control and possession.

73. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to the Cook Defendants.

74. As a result of this condition or these conditions, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

75. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss is yet to be determined.

COUNT V
FRAUD

76. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

77. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, setting specifications for, licensing, manufacturing, preparing, packaging, maintaining, labeling, compounding, assembling, processing, promoting, selling, distributing, and marketing Cook Gunther Tulip™ IVC filters and Cook Gunther Tulip™ IVC filters.

78. At the time Plaintiff was implanted the Cook Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed, marketed, and sold into the stream of commerce the Cook Gunther Tulip™ IVC filter placed in her body.

79. At all times relevant to this action, the Cook Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted,

marketed, sold, and distributed into the stream of commerce the Gunther Tulip™ and Gunther Tulip™ IVC filters for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

80. The Cook Defendants falsely and fraudulently represented to Plaintiff, her physicians, and other members of the general public, that the Cook Gunther Tulip™ IVC filter:

a. Has been proven to effectively prevent pulmonary embolism;

b. Was self-centering and offered efficient clot trapping;

c. Was designed to minimize the most common filter complications;

d. The anchors on the filter created secure, atraumatic attachments to the caval wall;

e. Provided enhanced retrievability giving an extended time for retrieval; and,

f. Could safely stay in place permanently in the body.

81. In the Clinical Study section of the Instructions for Use provided to the physicians who were implanting the Cook Gunther Tulip™ IVC filter, including the filter implanted in the Plaintiff, the Cook Defendants states a clinical study involved a 74 patient cohort, with follow-up conducted at 1 month (60 of 69 possible patients), 3 months (50 of 58 possible patients) and 6 months (37 of 41 possible patients) consisting of clinical exam and imaging by X-ray and duplex ultrasound, no device related major adverse events (defined as hemorrhage, perforation, death, occlusion, filter fracture or significant filter migration) occurred.

82. The representations by the Cook Defendants were, in fact, false. The true facts were that the Cook Gunther Tulip™ IVC filter is not safe for long term/permanent surgical implantation for said purposes, it has not been proven the filter effectively prevents pulmonary embolism; the filter presents a high risk of perforation through the caval wall, the filter has a high risk for fracture, and the filter is not safe for permanent placement in the body. In the clinic study that was presented to physicians through the instructions for use, the IFU gives a false sense of safety by reporting on a subset of OUS patients regarding high rates of successful retrieval rates and no complications, which has been shown to be incorrect. The retrieval rates listed give a false sense of safety when the OUS study did not address safety, and falsified complication and perforation rates. The Gunther Tulip™ filter was and is, in fact, dangerous to the health and body of Plaintiff.

83. When the Cook Defendants made the aforesaid representations, and others, they knew them to be false, and those representations were made by the Cook Defendants with the intent to defraud and deceive Plaintiff and her physicians, and with the intent to induce Plaintiff and her physicians to act in the manner herein alleged, *i.e.*, to use the Cook Gunther Tulip™ IVC filter in surgery.

84. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss is yet to be determined.

COUNT VI
NEGLIGENT MISREPRESENTATION

85. Plaintiff realleges and incorporates by reference each and every allegation

contained in the foregoing paragraphs as though fully set forth herein.

86. At all times relevant to this cause, and as detailed herein, the Cook Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information or omitted or failed to disclose material information concerning Cook IVC filters and the Cook Gunther Tulip™ filter; including, but not limited to, misrepresentations relating to the safety, efficacy, failure rate and approved uses of the Cook IVC filter.

87. The Cook Defendants falsely represented to Plaintiff, her physicians, and other members of the general public, that the Cook Gunther Tulip™ IVC filter:

a. Was proven to be hemodynamically effective;

b. Has been proven to effectively prevent pulmonary embolism;

c. Was self-centering and offered efficient clot trapping;

d. Was designed to minimize the most common filter complications;

e. The anchors on the filter created secure atraumatic attachments to the caval wall;

f. Provided enhanced retrievability giving an extended time for retrieval; and

g. Could safely stay in place permanently in the body.

88. In the Clinical Study section of the Instructions for Use provided to the physicians who were implanting the Cook Gunther Tulip™ IVC filter, including the filter implanted in the Plaintiff, the Cook Defendants states a clinical study involved a 74 patient cohort, with follow-up conducted at 1 month (60 of 69 possible patients), 3 months (50 of 58 possible patients) and 6 months (37 of 41 possible patients) consisting of clinical exam and imaging by X-ray and duplex ultrasound, no device related major adverse events

(defined as hemorrhage, perforation, death, occlusion, filter fracture or significant filter migration) occurred.

89. The representations by the Cook Defendants were, in fact, false. The true facts were that the Cook Gunther Tulip™ IVC filter is not safe for long term/permanent surgical implantation for said purposes, it has not been proven the filter effectively prevents pulmonary embolism; the filter presents a high risk of perforation through the caval wall, the filter has a high risk for fracture, and the filter is not safe for permanent placement in the body. In the clinic study that was presented to physicians through the instructions for use, the IFU gives a false sense of safety by reporting on a subset of OUS patients regarding high rates of successful retrieval rates and no complications, which has been shown to be incorrect. The retrieval rates listed give a false sense of safety when the OUS study did not address safety, and falsified complication and perforation rates. The Gunther Tulip™ filter was and is, in fact, dangerous to the health and body of Plaintiff.

90. The information distributed by the Cook Defendants to the public, the medical community and Plaintiff's health care providers, including reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, was false and misleading, and contained omissions and concealment of truth about the dangers of the use of the Cook IVC filters, including the Cook Gunther Tulip™ filter. The Cook Defendants made the foregoing misrepresentations knowing that they were false and/or without reasonable basis in fact. These materials included instructions for use and warning document that was included in the packaging of the Cook Gunther Tulip™ filter that was implanted in Plaintiff.

91. The Cook Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Cook IVC filters, including the Gunther Tulip™ IVC filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use Cook IVC filters, including the Cook Gunther Tulip™ filter.

92. In reliance upon the false and negligent misrepresentations and omissions made by the Cook Defendants, Plaintiff, Plaintiff's health care providers and the Plaintiff's agents were induced to, and did use the Cook Gunther Tulip™ filter, thereby causing Plaintiff to sustain severe personal injuries.

93. The Cook Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by the Cook Defendants and would not have prescribed and implanted same if the true facts regarding the device had not been concealed and misrepresented by the Cook Defendants.

94. The Cook Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Cook filter.

95. At the time Cook Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Cook Gunther Tulip™ filter, Plaintiff, Plaintiff's health care providers and the Plaintiff's agents were unaware of said Cook Defendants' negligent misrepresentations and omissions.

96. Plaintiff, Plaintiff's health care providers, the Plaintiff's agents and general medical community reasonably relied upon misrepresentations and omissions made by the Cook Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Cook Gunther Tulip™ filter.

97. Plaintiff, Plaintiff's health care provider's and Plaintiff's agents' reliance on the foregoing misrepresentations and omissions by Cook Defendants were the direct and proximate cause of Plaintiff's injuries as described herein.

COUNT VII
PUNITIVE DAMAGES

98. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

99. The actions and inactions of all the Defendants, and or alternatively the employees or agents of Defendants, and their predecessors-in-interest, whether taken separately, or together, were of such a character as to constitute a pattern or practice of intentional wrongful conduct and/or malice resulting in the injury and damages of Plaintiff Yolanda Munoz.

100. More specifically, Defendants, or alternatively the employees or agents of Defendants, and their predecessors-in-interest, consciously and/or deliberately concealed

risks associated with their product and nevertheless proceeded with conscious indifference to the rights, safety, and welfare of Plaintiff Yolanda Munoz by failing to act to disclose these risks to her or her healthcare professionals.

101. Defendants are guilty of oppression, fraud, and/or malice, express or implied for which they should be held liable in punitive damages to Plaintiff Yolanda Munoz.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiff, Yolanda Munoz, prays for relief on the entire complaint, as follows:

a. Judgment to be entered against all Defendants on all causes of action of the Complaint, including but not limited to:

   1. Pain and suffering;

   2. Mental anguish in the past and which, in reasonable probability, she will sustain in the future; and,

   3. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses she will need in the future;

b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post-judgment interest on the judgments entered in Plaintiff's behalf; and,

d. Such other relief the court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

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DATED August 15, 2022.

Respectfully Submitted,

/s/ Jennifer Rethemeier

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